Draft Meeting Summary
Cardiac Services Advisory Committee
Wednesday, November 18, 2015
MHCC, 4160 Patterson Avenue, Baltimore, MD 21215

Member Attendees:
Thomas Aversano, M.D. (by phone)
Jesus Cepero, M.D. (by phone)
Joseph Cinderella, M.D. (by phone- substitute for Steve Hearne, M.D.)
John Conte, M.D.
Blair Eig, M.D. (by phone)
Christopher Haas (by phone)
Josemartin Ilao
Rawn Salenger, M.D. (substitute for James Gammie, M.D)
Stuart Seides, M.D. (by phone)
Jerome Segal, M.D.
Ben Steffen, Executive Director, MHCC
William Thomas, M.D.
Stafford Warren, M.D.
David Zimrin, M.D.

MHCC Staff Attendees:
Paul Parker, Director, Health Care Facilities Planning & Development
Eileen Fleck, Chief, Acute Care Policy and Planning
Theressa Lee, MHCC (by phone)
Kathy Ruben, MHCC

Introduction

The Cardiac Services Advisory Committee (CSAC) meeting convened at approximately 6:20 pm. Eileen Fleck, Chief, Acute Care Policy and Planning thanked everyone for attending the meeting. Ms. Fleck explained that members would be discussing strategies for re-evaluating the scope of cardiac surgery. Ms. Fleck then asked the meeting participants, including those who were participating by phone, to introduce themselves.

Following introductions, Ben Steffen, Executive Director of the Maryland Health Care Commission (MHCC), thanked the CSAC members for attending the meeting, as well as for their work before the adoption of final regulations. He then summarized the agenda and goals for this meeting. He explained that the focus of the meeting will be on how to move forward recognizing that there was not consensus within the group on defining codes for cardiac or open heart surgery. The purpose of the meeting is not to discuss specific codes, but rather to discuss the process for resolving classification differences and to determine how to get input from CSAC members, as well as how to engage others in the process including those from non-cardiac

surgery hospitals. He also noted that of particular concern is how to align ICD-10 codes with ICD-9 codes because the cardiac utilization projection, which is used for Certificate of Need (CON) reviews, uses six years of data and will be based on both sets of codes for several years.

Mr. Steffen noted that there was a set of policy questions for CSAC members to discuss at the meeting, including whether the cardiac regulations should continue to have two definitions, one for "open heart surgery" and another for "cardiac surgery." Alternatively, a single definition for cardiac surgery could be developed. Because some procedures are difficult to classify, Mr. Steffen said that the CSAC would also discuss new coding structures based on the ICD-9 and ICD-10 codes. Finally, he added that the group will revisit the issue of volume standards and consider if the volume standards should be changed based on expansion of the definition of cardiac surgery and the list of procedures that count towards the volume standard. Mr. Steffen then turned the meeting back over to Ms. Fleck.

Update on COMAR 10.24.17

Ms. Fleck noted that the new final regulation COMAR 10.24.17 became effective November 9, 2015. She said that she has received some questions asking for clarification of how to conduct external reviews. Ms. Fleck assured CSAC members that MHCC staff will distribute additional information about the new regulations to help people better understand them.

Ms. Fleck noted that MHCC had recently received two applications for Certificate of Conformance reviews. She noted that one application is from Holy Cross Health regarding the establishment of primary PCI services at the Holy Cross Germantown Hospital. The second application is from the University of Maryland Shore Medical Center at Easton for establishing both primary and elective PCI services.

Ms. Fleck stated that the first Certificate of Ongoing Performance reviews for cardiac surgery are scheduled for February 2016, but there may be an adjustment in the schedule because calculations required for these reviews have not been completed yet. The calculations required allow for a comparison of each hospital's operative mortality rate for coronary artery bypass surgery to the statewide average. MHCC staff expects to rely on the Society of Thoracic Surgeons (STS) to perform these calculations. However, MHCC has not finalized a contract with STS for this work yet. Another potential reason for adjusting the schedule adjustment is that the results of the STS data audit are not yet available. Ms. Fleck noted that any schedule change will be posted in the *Maryland Register*. Dr. Seides asked if instituting a new primary PCI program or primary and elective PCI program would require a CON. Ms. Fleck replied that a Certificate of Conformance review is required rather than a CON review. She noted that the two are similar in terms of the requirement to demonstrate the need for the proposed project. Mr. Steffen said that the most significant difference between the two processes is that with a Certificate of Conformance application, there is not interested party participation. Both reviews are both based on criteria contained in the State Health Plan.

Approach for Re-evaluating the Scope of Cardiac Surgery

For the sake of time, Mr. Steffen suggested that the group discuss the key process questions and skip reviewing MHCC staff's objectives.

Key Process Questions

Mr. Steffen asked CSAC members how MHCC should approach defining the range of procedure codes to evaluate for inclusion in a definition of cardiac surgery while minimizing the onerousness of the process. Mr. Steffen noted that MHCC staff recognized the lack of complete agreement in the previous process, but MHCC staff's perception of the level of consensus varied based on the mix of participants in discussions. He commented that it might be helpful to have a consistent group of participants throughout the process and fewer, longer meetings. He asked if it was better for members to consider the entire list of codes or to hone in on a shorter list of codes where there has been disagreement among stakeholders. Mr. Steffen added that the cardiac surgeons in the group recently provided a list of recommendations for the categorization of the cardiac surgery codes to MHCC staff. This list was distributed by e-mail shortly before the CSAC meeting. Ms. Fleck suggested that Dr. John Conte explain the process that was used by the Maryland Cardiac Surgery Quality Initiative (MCSQI) to develop its list. MCSQI an independent collaborative group that includes all ten of the cardiac surgery programs in Maryland whose sole mission is to examine the quality of cardiac services and outcomes in the state.

Dr. Conte explained that members of MCSQI reviewed the list of ICD-9 codes for cardiac procedures and for each code considered whether the procedure was consistent with the active practice of cardiac surgery in 2015. The intent was to be as inclusive as possible, using a set of four criteria. He further explained that because the scope of cardiac surgery will change over time MCSQI focused on identifying principles that could be applied currently and in the future. The four core principles used to categorize codes as cardiac surgery included:

- Incision in the chest
- Direct contact with the heart
- The use of cardio-pulmonary bypass
- Operation on the thoracic-aorta or great vessels

Dr. Conte explained that members of MCSQI believe that there should be clarity and transparency in defining cardiac surgery. Dr. Conte explained that while the State has an additional mission that includes qualitatively and quantitatively evaluating cardiac surgery programs, MCSQI's goal was to define cardiac surgery inclusively.

Dr. Conte added that the State may use only a subset of codes for evaluating cardiac surgery program's compliance with volume requirements, but that decision is distinct from defining cardiac surgery. Dr. Conte suggested that the State should define cardiac surgery based on the criteria that the MHCC decides upon, and then decide how to evaluate programs based on those codes, whether it is inclusive of all codes or a subset of codes. Mr. Steffen thanked Dr. Conte and asked if anyone had questions.

Dr. Stuart Seides commented that he only briefly reviewed MCSQI's categorization of the ICD-9 codes, but it is very sensible and fulfills the mandate described by Dr. Conte. He also commented that the methodology as well as the handout simplifies and clarifies the process. He added that it is possible to get so wrapped up in definitions or counting that you forget the

purpose of the counting. Josemartin Ilao spoke from the patient's perspective expressing concern that defining a procedure as open heart surgery instead of cardiac surgery would affect the decisions made by insurance companies with regard to coverage for certain patients.

Mr. Steffen then asked Dr. Conte a question about the handout from MCSQI. He asked Dr. Conte to explain the last column where MCSQI recommended a new category of procedures that are not cardiac surgery but should only be performed at a cardiac surgery center. Dr. Conte explained that there are ICD-9 codes for procedures that do not meet the four core principles that MCSQI members agreed should define cardiac surgery. For example, Dr. Conte noted that in the early days a closed heart valvotomy was performed by a surgeon sticking his or her fingers in the heart and fracturing valves. He added that today most people would agree that a balloon, aortic, mitral, or tricuspid valvuloplasty is a procedure that is not cardiac surgery. However, he noted that due to the potential complications for patients undergoing some cardiac procedures, other than cardiac surgery, it is in the best interest of these patients to be in a hospital with immediate access to cardiac surgery. Dr. Conte commented that some people may ask why PCI services are not among those limited to hospitals with a cardiac surgery program. His answer is that research has demonstrated the safety of performing PCI services at hospitals without cardiac surgery on-site, and there are certain tools and options available for handling complications that do not exist for certain other cardiac procedures.

Dr. Jerome Segal agreed with Dr. Conte regarding the research on the safety of PCI services at hospitals without a cardiac surgery programs and that certain cardiac procedures, other than cardiac surgery, have complications that may require bypass and should be limited to hospitals with a cardiac surgery program. Ms. Fleck asked if members of MCSQI considered having a separate category for exceptional or rare cases when cardiac surgery may be performed at a hospital without a cardiac surgery program. Dr. Conte responded that MCSQI members did consider those situations. He gave the example of a patient with an aortic dissection who cannot be transferred to a hospital with cardiac surgery, and so a surgeon takes the patient to an operating room to try and repair the aorta in order to save the patient's life. Other than this example, Dr. Conte commented that very few procedures do not meet two or more of the criteria chosen by MCSQI members to define cardiac surgery. Dr. Conte also added that the framework developed was one that anyone could apply to determine whether a procedure fits the definition of cardiac surgery.

Mr. Steffen noted that there appeared to be agreement among the cardiac surgeons who are CSAC members and within the MCSQI. He then asked for recommendations for engaging other CSAC members who are not cardiac surgeons. Dr. Seides replied that the approach taken by Dr. Conte and his colleagues was an enlightened approach that will serve the group well in the future. He added that it was difficult to conceive that others would disagree with the proposal of MCSQI. Dr. David Zimrin agreed with Dr. Seides, but suggested that the list be pared down to include only the potentially controversial procedures.

Mr. Steffen said he would like to have consensus among CSAC members before circulating the list externally. Dr. William Thomas suggested that the list should be edited, and the terminology should be clarified; the list could then be circulated to the entire advisory

committee before circulating more widely. Dr. Conte expressed appreciation for the comments of other CSAC members. He also suggested starting with the list of codes in COMAR 10.24.17 and flagging codes that MCSQI proposes adding or deleting. He said that approximately ten ICD-9 codes should probably be discussed in detail. Ms. Fleck asked if circulating an email message would be effective for this process. Dr. Conte commented that using email would be fine, as long as everyone who wanted to be included was on the list. Mr. Steffen noted that the purpose at this stage is to build consensus within the CSAC. He then asked if MCSQI could create the document that Dr. Conte had just described. Dr. Conte affirmed that the MCSQI could do it fairly quickly. Dr. Stafford Warren noted that it would be helpful to flag the ICD-9 codes that have been deemed controversial and include the four criteria used to evaluate the ICD-9 codes. Dr. Conte agreed with Dr. Warren's suggestions and added that a summary of the discussion about the codes would also be included. Mr. Steffen asked if there were any additional comments before moving on to the next discussion question. There were none.

Before proceeding with the next discussion question, Mr. Steffen provided some background information. He explained that MHCC staff use the hospital discharge abstract to identify cardiac surgery cases, based on the ICD-9 procedures codes included for each record. In reviewing the hospital discharge abstract, MHCC staff noted that cardiac surgery procedures were reported at hospitals without cardiac surgery programs. Mr. Steffen noted that, in some cases, these hospitals were adamant that certain cardiac surgery procedures should be permitted at hospitals without cardiac surgery programs. Mr. Steffen asked how best to reach out to these stakeholders and include them. Dr. Conte agreed that it is important to reach out to the non-cardiac surgery hospitals to explain the rationale for this list as well as the outcomes. He added that it is important to find out the methodology for coding at hospitals without cardiac surgery programs that are reporting cardiac surgery, including who handles the coding. He said that the issue may be miscoding by surgeons. He also suggested that there should be a methodology developed for evaluating coding practices.

Dr. Thomas commented that he found it difficult to identify ICD-9 codes on MCSQI's list of cardiac surgery codes that would be delineated as a privilege for surgeons at hospitals without a cardiac surgery program. Ms. Fleck responded that the pericardiectomy procedure has been controversial. Representatives for hospitals without cardiac surgery programs have presented rationales for why it is acceptable to do the procedure at their hospitals. Dr. Thomas commented that the pericardiectomy was the only procedure that he was debating. He added that he would expect most surgeons at hospitals without a cardiac surgery program to be performing pericardiotomies not pericardiectomies. Dr. Conte agreed that probably more pericardiotomies were performed, and he noted that the issue had been contentious over the past six months. He gave additional examples of other procedures that may be regarded as cardiac surgery that may be performed by vascular surgeons. Specifically, he mentioned patients with athleroscelorisis of their innominate or carotid arteries. The condition could be treated with bypass procedures, but it would be a short-term treatment that is not safe or in the patient's best interest. Dr. Warren asked whether the ICD-10 codes distinguished between a partial and complete pericardiectomy; there are not distinct ICD-9 codes for each. Both Mr. Steffen and Ms. Fleck noted that the ICD-10 procedure codes do not make the distinction either. Several workgroup members agreed that ICD-10 would not be helpful in distinguishing partial and complete pericardiectomy. Dr. Segal

commented that he spoke to a surgeon at his hospital and was told that resecting a mediastinal lung tumor is one situation where a large section of the pericardium may need to be removed. He noted that it is a gray area. Dr. Blair Eig commented that MHCC staff contacted him about one case, in which a pericardial cyst was removed, that was reported as a pericardiectomy, and he agreed that there seemed to be a gray area. However, he also commented that losing one case, due to a change in the definition of cardiac surgery, would not be a great loss.

Mr. Steffen said that it may be better for the committee to think about how to deal broadly with cardiac procedures that fall in a gray area rather than looking at specific individual cases. Ms. Fleck noted, however, that in some cases it may be helpful to know about the specific circumstances. Dr. Conte then made three points. First, he noted that there is a code for removal of a pericardial cyst, and using the code for a pericardiectomy is an example of miscoding. Second, he explained that MCSQI's framework for defining cardiac surgery based on four criteria will help separate patients who have a limited pericardial resection due to tumor adherence from those who have restrictive or constrictive disease that requires a heart-lung machine. Finally, he added that the four criteria used by MCSQI help delineate the gray areas.

Mr. Steffen summarized the discussion by stating that there is consensus that representatives for hospitals without cardiac surgery programs that are not part of the CSAC need to be included. He added that it may not be possible to differentiate the scope of services that should only be done in a cardiac surgery center given the current coding system, so there should be general criteria for determining how to handle gray areas. Dr. Conte commented that he anticipated one of the sticking points may be whether a procedure counts as part of the minimum volume requirement. Dr. Conte added that if the State decides to exclude codes that fall in a gray area from the volume requirement, then those issues should be easily worked out through a discussion. He suggested that the State could pick five of the most common procedures to determine whether a hospital meets volume requirements. He also emphasized that, in the interest of public safety, a list of cardiac procedures that are most safely performed at a cardiac surgery center should be widely distributed. Lastly, Dr. Conte thanked Dr. Rawn Salenger for his extensive work as one of the architects of MCSQI's categorization of ICD-9 procedure codes.

Mr. Steffen also thanked Dr. Salenger for his work and proceeded to the next discussion question. He asked CSAC members what approach should be used to define cardiac surgery using ICD procedure codes, given the recent switch to using ICD-10 procedures codes. He also reminded members that this issue has to be resolved because MHCC will be relying on discharge abstract data with both ICD-9 and ICD-10 codes for several years for the cardiac utilization projection. He noted that redefining ICD-9 codes as ICD-10 codes would be extremely challenging, but re-coding from ICD-10 back to ICD-9 codes is easier. He added that resolving this issue will both provide clarity to hospitals and allow for an accurate utilization projection. Mr. Steffen then turned the meeting over to Ms. Fleck to lead the discussion on coding.

Ms. Fleck reiterated that the State will have to address the use of the ICD-10 codes in implementing COMAR 10.24.17, and she suggested that it may be helpful to address the conversion from ICD-9 to ICD-10 codes now. Dr. Conte suggested that the MHCC may want to identify coding experts and get one of these experts to act as a consultant. He agreed that both

sets of codes will be in use for a window of time, and eventually there may be conversion software that makes the process of conversion easy. He also stated that the MCSQI may need to go back and take a look at how additional ICD-9 and ICD-10 codes compare to each other because the limited codes that have been examined do not add a lot of clarity.

Mr. Steffen suggested hiring an expert to "crosswalk" the ICD-10 codes to ICD-9 codes. He commented that he was not sure if the MHCC could afford an expert, but he asked for feedback on whether it would be a good starting point. Dr. Thomas said that it may be worth checking with professional coders within institutions that have cardiac surgery since these hospitals may have already developed a crosswalk. Dr. Conte agreed with Dr. Thomas, and he noted that the Society of Thoracic Surgeons (STS) has a work group devoted to coding. Ms. Fleck said that she would follow up with STS on this issue. Dr. Warren asked if there was a mechanism in place for looking at cardiac procedures that fall in a gray area, such as a subgroup of members that evaluate those cases. Ms. Fleck said that it may be difficult to implement, unless there was a specific concern raised. Mr. Steffen commented that MHCC staff may be concerned if, when a hospital applies for a Certificate of Ongoing Performance, many cases fall in a gray area. He indicated that MHCC staff would have to check with legal counsel as to whether a subgroup of the CSAC could be involved in evaluating cases that fall in a gray area. Mr. Steffen added that his recollection is that only a small number of cases fell in a gray area for individual hospitals. He noted that having access to STS coding experts may be very helpful. Mr. Steffen then suggested that Ms. Fleck lead the discussion of key policy questions.

Key Policy Questions

Ms. Fleck asked CSAC members whether the regulations should continue to include definitions of open heart surgery and cardiac surgery and whether a single definition of cardiac surgery could be developed. She said that MHCC staff recommends eliminating the term "open heart surgery" because it fails to fully capture what is regarded as cardiac surgery. In addition, she explained that part of the rationale for using the term open heart surgery was to use it to define which cardiac procedures would count for the purpose of evaluating compliance with the volume standards. Dr. Salenger agreed with Ms. Fleck that the terminology is confusing. He said that the CSAC needs to accurately define cardiac surgery and then determine which cardiac procedures should be counted toward the volume standards.

Mr. Ilao commented that the proposed change may minimize some of the confusion for professionals, but he expressed concern that patients might regard the switch from open heart surgery to cardiac surgery as minimizing the significance of the surgery. Dr. Conte thanked Mr. Ilao for bringing up the patients' perspective, and offered to clarify the significance of the proposed changed. He explained that Maryland is the only state that he knows of that does not use the terms cardiac surgery and open heart surgery interchangeably, and the change would not affect patients. Dr. Warren also addressed the concern raised by Mr. Ilao. Mr. Ilao thanked both physicians for clarifying the issue for him. Mr. Steffen commented that he was pleased that Dr. Conte and Dr. Salenger agreed with MHCC staff that the term "open heart surgery" should be removed from the regulations, and a subset of codes could be used to define compliance with volume standards.

Mr. Steffen then moved on to the second policy question. He asked whether the ICD-9 or ICD-10 codes alone identify pericardiectomies that can be safely and appropriately performed by a thoracic surgeon at hospitals without a cardiac surgery program. He also asked if using CPT-4 codes in addition to ICD-9 and ICD-10 codes would help provide additional clarity. Dr. Conte responded that the CPT-4 codes would not help provide additional clarity. Ms. Fleck then asked whether it would be useful to have detailed information about the patient circumstances for some of the cardiac procedures that fall in a gray area.

Dr. Salenger said that there is a gray area for thoracic oncologic procedures that are first time pericardial operations without pericardial stripping, if there is no separate procedure code to capture the pericardial procedure. Dr. Salenger also stated that pericardial stripping should only be performed at a cardiac surgery center. Ms. Fleck said that she did think there was unanimity that a complete pericardiectomy should be limited to hospital with cardiac surgery programs. However, she has heard from one person who disagrees.

Dr. Conte commented that there were a few situations where it may be necessary for a thoracic surgeon to be able to perform a pericardiectomy at a hospital without cardiac surgery, as was mentioned earlier, such as oncologic procedures. He noted that a surgeon may not be able to anticipate the extent of involvement with the pericardium even with imaging prior to surgery. He also noted that MCSQI's categorization of ICD-9 codes included a category for cardiac procedures that should only count as cardiac surgery if extracorporeal circulation is performed in conjunction with the procedure. He acknowledged that there will always be gray area procedures, and reviewing operative reports would clarify the procedure actually performed and be beneficial. However, he also suggested that gray area cases would be so rare that the MHCC probably would not want to go through that effort except during a detailed review of borderline programs.

Ms. Fleck responded that her suggestion pertained to the CSAC's current task of reconsidering the definition of cardiac surgery, rather than an approach to ongoing oversight by MHCC. Dr. Conte responded that part of the gray area is the limitation of the language. For example, he noted that whenever you remove a small amount or a large amount tissue in a surgical procedure, it will be an "ectomy." He added that treatment of constrictive or restrictive disease through performing pericardial stripping (a pericardiectomy) is a major, challenging operation, but to excise part of the pericardium due to a tumor is usually not as difficult. However, the limitations of coding results in grouping these procedures under the same code.

Dr. Thomas commented that he would not expect gray area cases, such as pericardiectomy procedures, to significantly impact a program, in terms of meeting volume requirements even if the gray area cases were not counted. Consequently, Dr. Thomas concluded that he would not expect the issue to be controversial. Mr. Steffen agreed that he would not expect it to be an issue for cardiac surgery programs. His concern is regarding the hospitals without cardiac surgery programs. He asked at what point the State should be alarmed by the number of gray area cases. For example, if a PCI program is being reviewed for a Certificate of Ongoing Performance, and there are a number of gray area cases, what number of gray area cases is acceptable. Dr. Thomas expressed concern about holding a PCI program accountable for the actions of a thoracic surgeon.

Dr. Segal expressed concern about limiting a thoracic surgeon's ability to do a proper resection, and he suggested that there is excessive concern about oversight of these rarely performed procedures. He added that the skills of individual surgeons should also be considered. Dr. Thomas commented that hospitals have boards that grant privileges, and the MHCC should not intervene in aspects of credentialing. Ms. Fleck agreed that Dr. Thomas's concern is valid, and she noted that patient safety matters too. Dr. Thomas commented that quality control issues are very different from limiting physicians from performing certain procedures or intervening in oversight within an institution; the latter would require discussion with all hospitals within the State. Mr. Steffen said that the gray areas should be discussed further, but there may not be an absolute resolution. He asked if there were additional comments. Dr. Salenger commented that because Maryland is a state where a CON is required to establish a cardiac surgery program, if the MHCC defines a procedure as cardiac surgery, then it should be performed only at a cardiac surgery center. He also commented that he did not share Dr. Thomas's concerns about infringing on the role of hospital boards as a result of defining cardiac surgery. Dr. Thomas clarified that he did not regard MCSQI's proposal as problematic.

The final policy question asked by Mr. Steffen was whether the State should consider changing the volume standards based on changes made to the definition of cardiac surgery and the list of procedures that count toward the volume standard. Dr. Conte commented that MCSQI members discussed the issue, and some members were very concerned about making any changes due to concerns about how the volume standards might change. Dr. Conte commented that he did not think there was a need to change the volume standards, but he recommends tracking the codes to evaluate any impacts. Dr. Seides and Dr. Salenger agreed with Dr. Conte. Dr. Segal said that he thought the volume standards were based on data from 30 years ago, for patients who primarily had bypass procedures, and if linked to quality, which he regards as questionable, then newer studies of the relationship between volume and outcomes should be evaluated. Dr. Conte again noted that the issue should be followed longitudinally. Mr. Ilao recommended that the MHCC inform consumers about the implications of removing references to open heart surgery and using the term cardiac surgery instead, so they understand that it is not problematic.

Next Steps

Mr. Steffen thanked the CSAC members for their participation and the MCSQI for its work. Mr. Steffen and Ms Fleck suggested adding some ICD-10 codes to the MCSQI document that had been distributed, for the shorter list of ICD-9 codes to be discussed. Mr. Steffen asked about the next scheduled meeting. Ms. Fleck said that a meeting had not been scheduled yet, but she suggested one potentially could be scheduled in January. She also stated that MHCC staff would circulate an email message to get feedback from CSAC members on the codes. Dr. Conte said that the MCSQI could get a revised document together in a few weeks for circulation among CSAC members. Ms. Fleck also stated that MHCC staff would investigate whether the STS coding group could be a resource. Mr. Steffen noted that Commission staff do not anticipate requesting approval of proposed regulations before April or May of 2016, due to the legislative session. Ms. Fleck thanked members of the Committee for their participation. The meeting was adjourned at approximately 8:05pm.